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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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CHARLES H. AARONSON,

MEMORANDUM & ORDER

09-CV-2487 (NGG) (RLM)

Plaintiff,

-against-

AMERICAN MEDICAL SYSTEMS, INC.,

Defendant.
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NICHOLAS G. GARAUFIS, United States District Judge.

Plaintiff Charles Aaronson ("Plaintiff") brings this products-liability suit against Defendant American Medical Systems, Inc. ("AMS") for damages arising from injuries he sustained using the AMS Ambicor Inflatable Penile Prosthesis (the "Ambicor").[1] (See Compl. (Docket Entry # 15) ¶ 9.) AMS moves to dismiss Plaintiff's Complaint, asserting that federal law preempts Plaintiff's state-law claims. (See Def. Mem. (Docket Entry # 15).) For the following reasons, Defendant's motion is denied without prejudice.

I. BACKGROUND

AMS designs and manufactures various medical devices, including the Ambicor. (Compl. ¶¶ 9-10.) In April 2006, Plaintiff's physician surgically implanted the Ambicor into Plaintiff's body. (Id. ¶ 12.) Plaintiff claims that a defect in the product caused him to suffer and sustain severe permanent injuries, including "side effects, bodily pain, emotional distress, mental anguish and disabilities." (Id. ¶ 14).

[1] Plaintiff also names "AMS AMBICOR" as a defendant. According to AMS, however, AMS Ambicor is neither a legal nor business entity. It is the name of the product at issue. (See Def. Mem. (Docket Entry # 15) 1 n.1.)

Plaintiff alleges that AMS (1) negligently designed, tested, inspected, created, manufactured, distributed, labeled, marketed, and sold the Ambicor and negligently failed to recall it from the market; (2) breached an express warranty that "consumers could safely use the [Ambicor] for sexual relations and for sexual gratification which would aid the [P]laintiff in attaining an erection etc."; (3) breached an implied warranty that the Ambicor was "safe, of merchantable quality, and fit for the ordinary purposes for which the product was intended"; (4) sold the Ambicor in a defective condition; and (5) failed to provide sufficient warnings of any danger associated with the Ambicor. (See id. ¶¶ 17-18, 23-25, 31-33, 41, 55-56.) Plaintiff seeks damages for personal injury, emotional distress, mental anguish, and "disabilities." (Id. ¶ 14.)

AMS argues that the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act preempt all of Plaintiff's state-law claims because the Food and Drug Administration ("FDA") granted pre-market approval for the Ambicor. See 21 U.S.C. § 360k; Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). In support of this argument, AMS offers an affidavit from its Regulatory Affairs Program Manager stating that the Ambicor is a Class III medical device, which successfully completed the FDA's "Product Development Protocol." (Bulger Aff. (Docket Entry # 15).) Plaintiff asserts that the Ambicor is not a Class III medical device. (Def. Mem. (Docket Entry # 14) ¶ 3.)

II. DISCUSSION

A. Standard of Review

Federal Rule of Civil Procedure 12(b)(6) allows for dismissal for "failure to state a claim upon which relief can be granted." In evaluating a motion to dismiss under Rule 12(b)(6), a court must "accept as true all factual statements alleged in the complaint and draw all reasonable inferences in favor of the non-moving party." Vietnam Ass'n for Victims of Agent Orange v.

Dow Chem. Co., 517 F.3d 104, 115 (2d Cir. 2008) (citation omitted). To survive a Rule 12(b)(6) motion, a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, — U.S. —, 129 S.Ct. 1937, 1949 (2009) (quoting Bell Atl. Corp. v. Twombly, 555 U.S. 544, 570 (2007)). A district court may grant a motion to dismiss based on federal preemption, if the defense can "easily be determined from the pleadings." Cf. Drake v. Lab. Corp. of America Holdings, 458 F.3d 48, 66 (2d Cir. 2006) (denying motion to dismiss when "preemption cannot be easily determined from the pleading" (internal quotation marks omitted)).

B. Federal Preemption

The MDA expressly preempts state requirements that are "different from, or in addition to, any [federal] requirement applicable" to a Class III device that has undergone federal safety review and received pre-market approval by the FDA.[2] 21 U.S.C. § 360k; see Riegel, 552 U.S. at 322. In Riegel, the Supreme Court held that § 360k preempted New York state claims—substantially similar to some of Plaintiff's claims—for imposing requirements that are different from or in addition to federal requirements.[3] Riegel, 552 U.S. at 320-21. The Supreme Court noted, however, that § 360k does not prevent a State from providing "parallel" damages remedies "for claims premised on a violation of FDA regulations." Id. at 330.

C. Application

Under these principles, the court cannot "easily determine[]" from the Complaint whether federal law preempts Plaintiff's state-law claims. See Drake, 458 F.3d at 66. Specifically, it is

[2] The MDA does not preempt state-law claims based on medical devices that received pre-market approval through the FDA's "substantial-equivalence" review under § 510(k). See Medtronic, Inc. v. Lohr, 518 U.S. 470, 492-94 (1996).

[3] Because the parties dispute whether the Ambicor is a Class III medical device and discovery has not yet occurred, the court declines to credit Defendant's affidavit and convert AMS's motion to dismiss into one for summary judgment under Federal Rule of Civil Procedure 12(d).

unclear (1) whether the Ambicor is a Class III medical device for which the FDA granted pre-market approval, triggering the MDA's preemption provision; and (2) if the Ambicor is such a device, whether Plaintiff's state-law claims are premised on violations of FDA regulations or on state requirements that are "different from, or in addition to, any requirement applicable" under federal law. See 21 U.S.C. § 360k.

III. CONCLUSION

Because the pleadings do not contain sufficient information to determine whether Plaintiff's claims are preempted by federal law, Defendant's motion to dismiss is denied without prejudice. The court refers the parties to Magistrate Judge Mann to conduct limited discovery on the issue of whether the Ambicor underwent federal safety review and received pre-market approval under the FDA's Product Development Protocol. If the evidence shows that the Ambicor is a Class III medical device for which the FDA granted pre-market approval, the court sua sponte directs Plaintiff, within fourteen days after the close of discovery, to provide a more definite statement for the bases of his state-law claims such that the court can determine whether they would fall into Riegel's exception for state-law claims that § 360k does not preempt. See Fed. R. Civ. P. 12(e). Following this limited discovery, Defendant may move for summary judgment based on federal preemption or any other appropriate ground.

SO ORDERED.

s/Nicholas G. Garaufis

Dated: Brooklyn, New York
September 3, 2010

NICHOLAS G. GARAUFIS
United States District Judge